

207,052

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: PERBELLINI ET AL. Examiner:  
Application No: 10/540,939 Group Art Unit: 1645  
Filing Date: June 23, 2005  
Title: MIXED ESTERS OF  
HYALURONIC ACID  
WITH RETINOIC AND  
BUTYRIC ACIDS

July 13, 2006

STATEMENT OF FILING BY EXPRESS MAIL 37 C.F.R. SECTION 1.10

This correspondence is being deposited with the United States Postal Service on July 13, 2006 in an envelope as "Express Mail Post Office to Addressee" Mail Label Number ER 059 677 057 US addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement (hereinafter sometimes referred to as "IDS") is submitted in accordance with 37 C.F.R. §§1.97 and 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. § 1.97, as it is filed:  
(Check one of the boxes opposite A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in the above-identified international application.

☒ B. before the mailing date of a first office action on the merits or before the mailing date of a first office action after the filing of a request for continued examination (RCE) under 37 C.F.R. § 1.114.

☐ C. after the times set forth in (A) and (B) above, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a notice of allowance under 37 C.F.R. §1.311, and the

necessary statement pursuant to 37 C.F.R. §1.97(e) appears below (see box "i") or the necessary fee is enclosed (see box "ii" below).

(check one of the boxes opposite "i" or "ii" below)

☐ i. (check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

☐ ii. A check for the fee set forth in 37 C.F.R. §1.17(p), presently believed to be \$ 180.00, is enclosed.

☐ D. after the times set forth in (A), (B), and (C) above, but before payment of the issue fee, since Applicant petitions for the consideration of this Information Disclosure Statement by a petition enclosed herewith pursuant to 37 C.F.R. §1.97(d)(2), a check for the petition fee set forth in 37 C.F.R. §1.17(i), presently believed to be \$ 130.00, is enclosed, and the necessary statement pursuant to 37 C.F.R. §1.97(e) appears below: (check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

2. In accordance with 37 C.F.R. §1.98(a)(1), this IDS includes a list on form PTO-1449 of all patents, publications, or other information submitted for consideration by the Office, incorporated into this IDS as an attachment hereto. Pursuant to 37 C.F.R. §1.98(b): (i) each U.S. patent listed is identified by patentee, patent number, and issue date; (ii) each foreign patent or published foreign patent application is identified by the country or patent office which issued the patent or published the application, an appropriate

document number, and the publication date indicated on the patent or published application; and (iii) each publication is identified by author (if any), title, relevant pages of the publication, date, and place of publication. A legible copy of each document listed is attached and incorporated into this IDS, except that no copy of any U.S. patent application is included pursuant to 37 C.F.R. §1.98(a)(2)(iii) and except as explained below. (check the boxes opposite A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) \_\_\_\_\_ is (are) substantively cumulative to document(s) \_\_\_\_\_, and, in accordance with 37 C.F.R. §1.98(c), only a copy of each of the latter document(s) is (are) attached.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon for an earlier filing date under 35 U.S.C. §120:

[insert application numbers and filing dates of prior applications]

These documents are identified by attaching hereto copies of the forms PTO-892 and/or PTO-1449 from the files of the prior application(s) and Applicant requests that they be considered and made of record in this application in accordance with 37 C.F.R. §1.98(d). Pursuant to 37 C.F.R. §1.98(d), copies of these documents need not be provided with this IDS. (check paragraphs 3 and/or 4, if applicable).

☐ 3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with 37 C.F.R. §§1.98(a)(3), 1.98(c), it is stated that: (check the applicable statement(s))

☐ English translation(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) is (are) enclosed and, thus no concise explanation of their relevance is required, (see M.P.E.P., §609, p. 600-92).

☐ English-language equivalent(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) which is (are) in fact translation(s) of the document(s) is (are) enclosed.

☐ The attached English-language version of a search report or other action by a foreign patent office in a counterpart foreign application which cites document(s) \_\_\_\_\_ and which indicates the degree of relevance found by the foreign office is submitted to satisfy the requirement for a concise explanation of the relevance of the document(s), (see M.P.E.P., §609, p. 600-93).

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

[insert concise explanation of relevance]

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on the attached sheet.

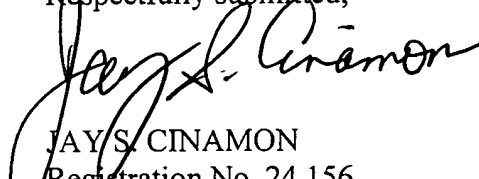
☐ 4. Other information being provided for the Examiner's consideration follows:

[insert other information]

5. In accordance with 37 C.F.R. §§1.97(g), 1.97(h), the filing of this IDS shall not be construed as a representation that a search has been made or as an admission that information cited in this IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b). Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

6. Please charge any deficiency or other fees or credit any refund or overpayment to Deposit Account No. 01-0035.

Respectfully submitted,

  
JAY S. CINAMON  
Registration No. 24,156  
Attorney for applicants

Date: July 13, 2006

ABELMAN, FRAYNE & SCHWAB  
666 Third Ave., 10th Floor  
New York, NY 10017-5621  
(212) 949-9022  
(212) 949-9190

wd\notar\7 13 06 perbellini.ids

Form PTO-1449 (Rev. 7-80)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket Control No. 207,052		Serial No. 10/540,939								
<b>LIST OF RELATED ART CITED BY APPLICANT</b> (Use several sheets if necessary) <div style="position: absolute; left: 10px; top: 10px; border: 1px solid black; border-radius: 50%; padding: 5px; text-align: center;">           U.S. PATENT &amp; TRADEMARK OFFICE            JUL 13 2006         </div>				Applicant <b>PERBELLINI ET AL.</b>										
				Filing Date June 23, 2005		Group 1645								
<b>U.S. PATENT DOCUMENTS</b>														
*Examiner Initial	AA	Document Number				Date	Name	Class	Subclass	Filing Date If Appropriate				
	AB													
	AC													
<b>FOREIGN PATENT DOCUMENTS</b>														
		Document Number				Date	Country	Class	Subclass	Translation YES NO				
	AL	W O 03	0	0	8	4	5	7	30.01.03	WIPO			X	
	AM													
	AN													
	AO													
	AP													
<b>OTHER RELATED ART</b> (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	M.J. Hill, "Bacterial Fermentation of Complex Carbohydrate in the Human Colon", <u>European Journal of Cancer Prevention</u> , Vol. 4, pgs. 353-358 (1995).												
	AS	Cummings, "Short Chain Fatty Acids in the Human Colon", <u>Gut</u> , Vol. 22, pgs. 763-779, 1981.												
	AT	Guilbaud et al., "Effects of Differentiation-Inducing Agents on Maturation of Human MCF-7 Breast Cancer Cells", <u>Journal of Cellular Physiology</u> , Volume 145, pgs. 162-172, (1990).												
	AU	Coradini et al., "Effect of Sodium Butyrate on Human Breast Cancer Cell Lines", <u>Cell Proliferation</u> , Vol. 30, pgs. 149-159, (1997).												
	AV	Coradini et al., "Sodium Butyrate Modulates Cell Cycle-Related Proteins in HT29 Human Colonic Adenocarcinoma Cells", <u>Cell Proliferation</u> , Vol. 33, pgs 139-146 (2000).												
Examiner							Date Considered							
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

2 of 3

Form PTO-1449 (Rev. 7-80)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket Control No. 207,052		Serial No. 10/540,939				
LIST OF RELATED ART CITED BY APPLICANT (Use several sheets if necessary)				Applicant      PERBELLINI ET AL.						
				Filing Date June 23, 2005		Group 1645				
U.S. PATENT DOCUMENTS										
*Examiner Initial		Document Number				Date	Name	Class	Subclass	Filing Date If Appropriate
	AA									
	AB									
	AC									
FOREIGN PATENT DOCUMENTS										
		Document Number				Date	Country	Class	Subclass	Translation YES   NO
	AL									
	AM									
	AN									
	AO									
	AP									
OTHER RELATED ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>										
	AR		Wisman et al., "Telomerase in Relation to Clinicopathologic Prognostic Factors and Survival in Cervical Cancer", <i>Int. J. Cancer</i> , Vol. 91, pgs. 658-664 (2001).							
	AS		Lotan, "Effects of Vitamin A and its Analogous (Retinoids) on Normal and Neoplastic Cells" <i>Biochimica et Biophysica Acta</i> , Vol. 605, pgs. 33-91 (1980).							
	AT		Douer et al., "Retinoic Acid Enhances Colony-Stimulating Factor-Induced Clonal Growth of Normal Human Myeloid Progenitor Cells in Vitro", <i>Experimental Cell Research</i> , Vol. 138, pgs. 193-198, (1982).							
	AU		Hansen et al., "Retinoids in Chemoprevention and Differentiation Therapy", <i>Carcinogenesis</i> , Vol. 21, pgs 1271-1279 (2000).							
	AV		DeLuca et al., "The Role of Vitamin A in Differentiation and Skin Carcinogenesis", <i>J. Nutr. Biochemistry</i> , Vol. 8, pgs. 426-437, (1997).							
Examiner						Date Considered				
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>										

373

Form PTO-1449 (Rev. 7-80)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket Control No. 207,052		Serial No. 10/540,939	
<b>LIST OF RELATED ART CITED BY APPLICANT</b> (Use several sheets if necessary)				Applicant <b>PERBELLINI ET AL.</b>			
				Filing Date June 23, 2005		Group 1645	
<b>U.S. PATENT DOCUMENTS</b>							
*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						
	AC						
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation YES   NO
	AL						
	AM						
	AN						
	AO						
	AP						
<b>OTHER RELATED ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	AR	Rudzki et al., "CD44 and the Adhesion of Neoplastic Cells", <u>J. Clin. Pathol. : Mol. Pathol.</u> , Vol. 50, pgs 57-71 (1997).					
	AS	Coradini et al., "Hyaluronic Acid as Drug Delivery for Sodium Butyrate: Improvement of the Anti-Proliferative Activity on a Breast-Cancer Cell Line", <u>Int. J. Cancer</u> , Vol. 81, pgs. 411-416 (1999).					
	AT	Jass et al., "Diet, Butyric Acid and Differentiation of Gastrointestinal Tract Tumours", <u>Medical Hypotheses</u> , Vol. 18, pgs 113-118, (1985).					
	AU						
	AV						
Examiner				Date Considered			
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							